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Massachusetts State Laboratory Institute

Lab News

July 1993

Ralph J. Timperi, M.P.H., Assistant Commissioner for Laboratory and Environmental Sciences

Briefs

Escherichia coli O157:H7...

Editorial Notes...
CLIA and Total Quality Management

Massachusetts Biologic and Laboratory Services Institute...
Governor files legislative proposal

Polio Virus...
Public Health Alert

Raccoon Rabies Virus Update...
Current Figures

Eastern Encephalitis...
Summer Surveillance Initiated

CLIA '88 Updates...
CLIAC Recommendations to CDC

Earning the Associates Degree

Newborn Screening...
HIV Seroprevalence Studies

Hemoglobinopathies

STD Surveillance...

SLI Notes...

New England ALTA News...

GOVERNMENT DOCUMENTS
COLLECTION

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Escherichia coli O157:H7

Escherichia coli O157:H7 was first recognized as an enteric pathogen in 1982, following its implication as the etiologic agent in two outbreaks of an unusual type of severe, bloody diarrhea called hemorrhagic colitis. These outbreaks were traced to contaminated hamburger.

As an emerging cause of foodborne illness, E. coli O157:H7 causes an estimated 10,000 to 20,000 cases of foodborne illness in the United States each year. In some persons, particularly children under 5 years of age and the elderly, an E. coli O157:H7 infection can also cause a complication called hemolytic uremic syndrome, in which the red blood cells are destroyed and the kidneys fail. About 2-7% of E. coli O157:H7 infections lead to this complication. In the United States, hemolytic uremic syndrome is the principal cause of acute kidney failure in children, and most cases of this syndrome are caused by E. coli O157:H7.

Because, E. coli O157:H7 is such an important public health concern, the Department of Public Health requests that all Hospital and Independent Clinical Laboratories assist in identifying the incidence of E. coli O157:H7 infections. Although not currently a reportable pathogen, this will change, when the Department updates its listing of reportable diseases.

Although, E. coli O157:H7 has become a significant enteric pathogen, few laboratories in Massachusetts routinely screen for it in stool cultures. The Department of Public Health requests that Massachusetts laboratories screen for this organism in stools from all patients with bloody diarrhea. It is important to note that E. coli O157:H7 cannot be detected by the methods used to isolate and identify the usual bacterial enteric pathogens.

Strains of E. coli O157:H7 ferment lactose rapidly and thus are indistinguishable from other E. coli on standard plate media. The suspect specimen must be tested on sorbitol-MacConkey (SMAC) agar.

The Enteric Laboratory at the State Laboratory Institute has found the following procedure effective for the isolation and identification of E. coli O157:H7. Stool specimens are plated on sorbitol-MacConkey agar (SMAC, available commercially), and incubated at 36° C, overnight. Colonies that do not ferment sorbitol within 24 hours are colorless and considered "suspicious for E. coli O157:H7"; other E. coli colonies will be pink to red in color. Suspicious colonies are then confirmed biochemically as well as by agglutination with E. coli O157 and H7 antisera.

It is essential that the manufacturer's instructions be followed in the use of their antisera and that both positive (known cultures of E. coli O157:H7) and negative controls be used when typing suspicious colonies. Laboratories that rarely isolate E. coli O157:H7 might prefer submitting isolates of sorbitol negative E. coli to our Enteric Reference Laboratory for confirmation.

The Enteric Reference Laboratory of the State Laboratory Institute will accept all suspected E. coli O157:H7 isolates for confirmatory identification. If you have any questions regarding the isolation, identification, or the submission of isolates, please contact the Enteric Laboratory (617-522-3700, x123) for assistance.

Laboratory isolation of Escherichia coli O157:H7 should be reported to the Bureau of Communicable Disease Control, Division of Epidemiology (617-522-3700, x427) in the same manner as other enteric pathogens.

305 South Street, Boston, Massachusetts 02130

Editorial Notes...

CLIA and Total Quality Management

Ralph Timperi, Assistant Commissioner for Laboratory and Environmental Sciences

As Public Health Laboratories are faced with mounting challenges, including new local, federal and state regulations, new methods of planning, prevention and continuous improvement can help us sharpen our vision and achieve our goals. An effective delivery system for this is the Total Quality Management (TQM) approach to laboratory operations.

In an effort to better serve you and as part of our total quality initiative at the State Laboratory Institute, we are especially interested in hearing from you about our programs and services. Please inform us of any compliments, suggestions, complaints and comments.

As we strive to meet new challenges and improve our service, we must take the responsibility to ensure that there is understanding, on an ongoing basis, as to what our laboratories do and how they do it. It is my hope that Lab News will provide just such a forum.

TQM should not be considered our end goal, but rather, the method our laboratories use to achieve the goal of higher quality. This means developing and maintaining systems for quality assurance (monitoring the complete testing process), implementing regular reviews of quality control and, lastly, ensuring that all employees are properly trained and provided with continuing education opportunities.

The Bureau of Laboratories and Environmental Sciences remains dedicated to the prevention of human illness caused by infectious, metabolic and environmental diseases.

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LAB NEWS is published quarterly by the staff of the Massachusetts State Laboratory Institute, 305 South St., Boston MA 02130 (Tel. 617-522-3700, x121). Complimentary subscriptions are available upon request, as are back issues as long as supplies last. LAB NEWS: *Editor,* Garry R. Greer; *Editorial Board:* Ralph J. *Timperi, M.P.H., Assistant Commissioner for Laboratory and Environmental Sciences, Harvey George Ph.D., Director of Diagnostic Laboratories*

Massachusetts Biologic and Laboratory Services Institute

Recently a legislative proposal which would establish the Massachusetts Biologic and Laboratory Sciences Institute (MBLSI) was filed by Governor William F. Weld. The creation of a Biologics Institute within the Department of Public Health, will preserve and maximize the public benefit of providing vaccines and low cost laboratory services within the Commonwealth.

This new organizational structure would preserve the stature of the Biologics Laboratory as an innovative research and manufacturing facility, while reducing the need for direct state support. The legislation would facilitate academic affiliations with local universities to enhance access to new technology and speed application of basic research, and facilitate the development of cooperative agreements with Biotech companies.

The Massachusetts State Laboratory Institute (SLI) has a long history of scientific excellence highlighted by original developments that have gained world recognition. These include, new screening technology for HIV, diagnostic tests for the detection of preventable diseases in newborns, and novel biologics, such as a series of immune globulins to prevent chickenpox, cytomegalovirus, bacterial meningitis, and viral respiratory infections in high-risk patients. The creation of the Massachusetts Biologic and Laboratory Services Institute would strengthen and increase the capabilities of the State Laboratory Institute.

Public Health Alert on Polio Virus

Wild Poliovirus Type 3 (PV3) was recently isolated from an unvaccinated community in Alberta, Canada. This community has reported direct contact with a Netherlands community experiencing 68 cases of poliomyelitis during September 1992-February 1993. Both strains have been determined to be virtually identical.

While no cases of paralytic poliomyelitis have been reported from the affected Alberta community, wild poliovirus can circulate in a population before paralytic disease occurs. Unvaccinated persons having contact with infected individuals are at significant risk of contracting the disease and subsequently spreading it to other unvaccinated persons. An outbreak originating in the Netherlands in 1978 caused by poliovirus type 1 spread from the Netherlands to Canada and then to the United States.

Polio is transmitted through the saliva and feces of infected persons. Although most persons infected with the polio virus develop no symptoms or have only mild disease, infection can lead to permanent paralysis and death in some individuals.

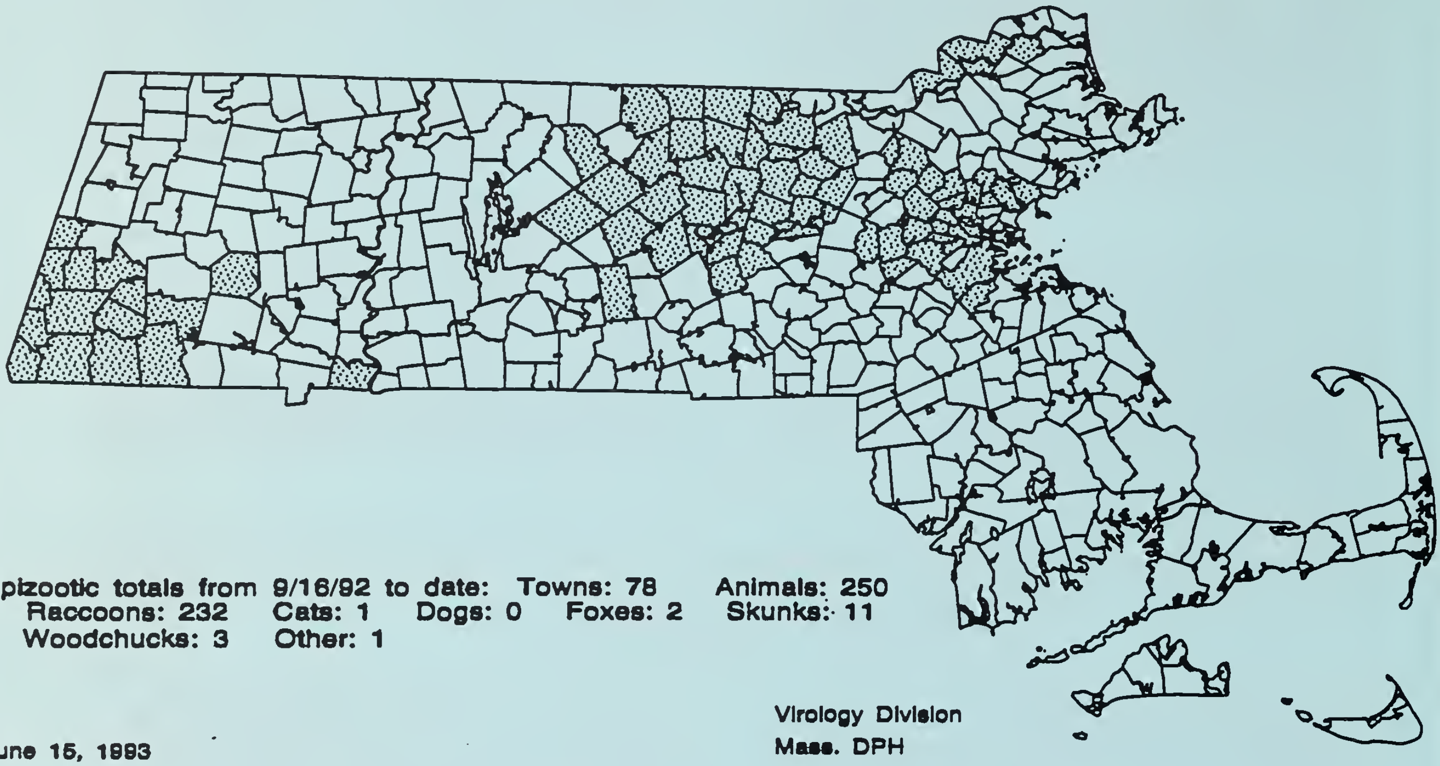
In response to these developments, any case of acute flaccid paralysis or aseptic meningitis occurring in a person who has not been vaccinated or received a complete series of polio vaccine should be reported to the Bureau of Communicable Disease Control, Division of Epidemiology, MDPH, (617) 522-3700 x420.

The collection of two stool samples (at least 24 hours apart) within 14 days after onset of symptoms will be required from each case to confirm the diagnosis. Specimens should be sent to the State Laboratory Institute for primary virus isolation. Instructions on specimen collection and submission can be obtained from the Viral Isolation Laboratory at (617) 522-3700 x196.

According to recommendations of the Advisory Committee on Immunization Practices (ACIP) any individual aged 18 years or less, found to be unvaccinated or not fully vaccinated should be encouraged to initiate or complete the primary series of oral polio vaccine (OPV).

Communities with philosophic or religious objection to vaccination are at greatest risk for acquiring polio. Therefore, OPV is recommended for all unvaccinated persons residing in these communities, including those aged > 18 years, because of its ability to limit community spread if polio virus is introduced.

Mid-Atlantic Raccoon Strain of Rabies Virus in Massachusetts
September 1992 to Date



Epizootic totals from 9/16/92 to date: Towns: 78 Animals: 250
Raccoons: 232 Cats: 1 Dogs: 0 Foxes: 2 Skunks: 11
Woodchucks: 3 Other: 1

June 15, 1993

Virology Division
Mass. DPH

Eastern Encephalitis Surveillance

Each year beginning in May and continuing into the fall, the Eastern Encephalitis Surveillance Program collects mosquitoes throughout eastern and southeastern Massachusetts to monitor mosquito abundance and the presence of eastern encephalitis virus (EEV). Trapping for mosquitoes begins in the southeastern portion of the state and extends northward as the season progresses. There are presently 21 established trap sites (see map, page 5) located in freshwater swamp areas.

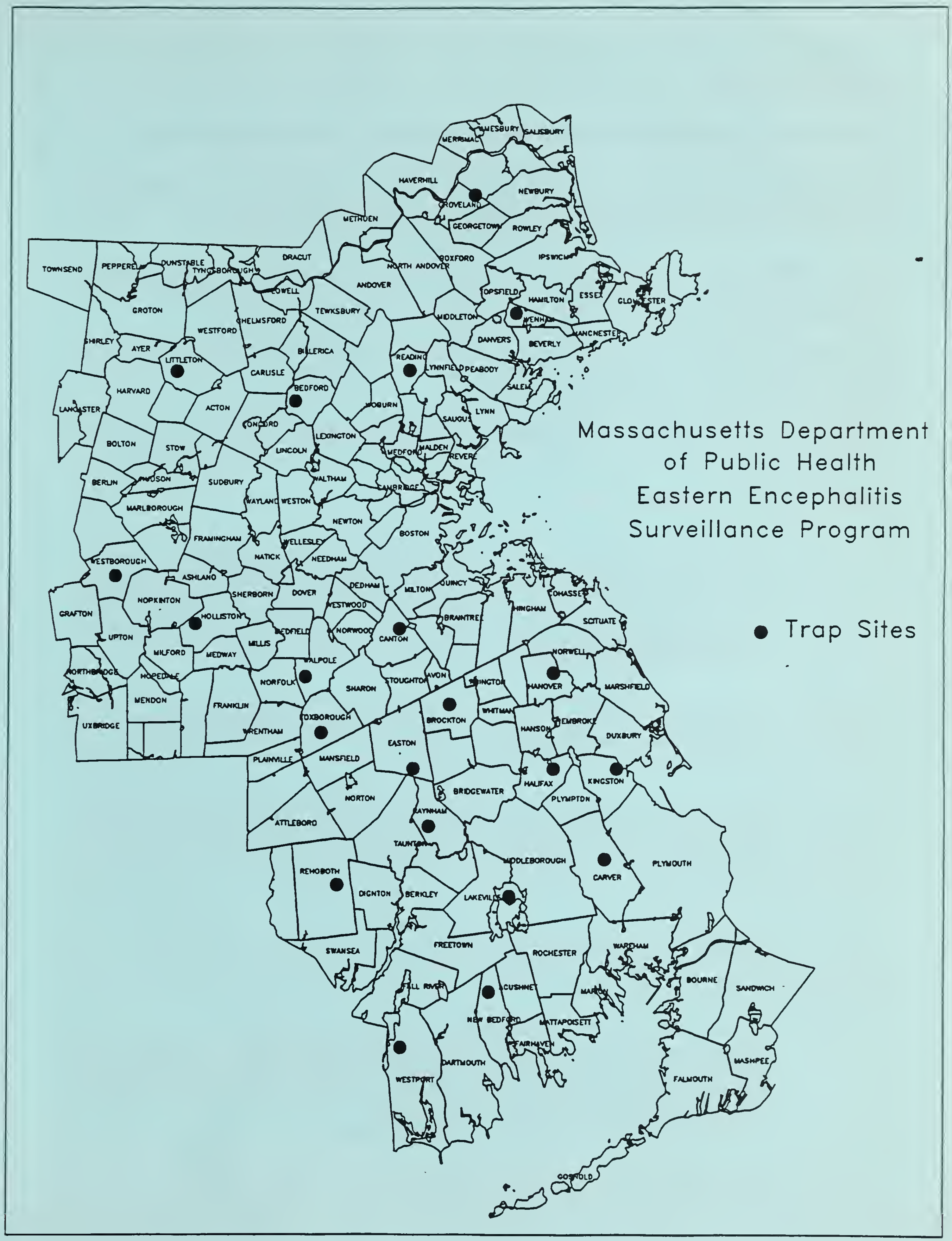
EEV is an arthropod-borne alphavirus of the family Togaviridae. The virus is endemic in certain wild bird species. Usually the virus remains within the confines of its avian host reservoir; however, occasionally disease outbreaks occur in horses and humans when the virus "spills over" into mosquito species that bite both birds and mammals.

Field staff collect mosquitoes twice weekly and bring them to the lab where female mosquitoes are sorted by species. Pools of up to 50 mosquitoes are tested for the presence of EE virus.

Mosquito pools are also tested for Highland J virus, an arbovirus that does not cause human disease but often serves as a precursor to EEV. Chick embryo tissue culture (CETC) followed by indirect immunofluorescence antibody assay (IFA) is used for detection, isolation and identification. In addition, mosquito abundance by species is compared to long term weekly population averages. Evidence of EEV in mosquitoes is an indication of increased risk of disease transmission; significant increases in populations indicate increased probability of transmission when EEV is present.

The surveillance program also tracks suspect human and equine cases of disease. Human and equine sera and cerebrospinal fluids (CSF) are tested for antibody by IFA and IgM capture enzyme immunoassay (EIA). CSF and brain tissue samples are tested for the presence of virus by plaque assay on CETC and are confirmed by plaque-reduction neutralization (PRNT).

As risk criteria indicate, advisories are issued and ongoing public education campaigns are intensified.



Massachusetts Department of Public Health Eastern Encephalitis Surveillance Program

● Trap Sites

CLIA '88 Updates

CLIAC Recommendations to the Secretary of Health and Human Services

The third Clinical Laboratory Improvement Advisory Committee (CLIAC) meeting was held in Atlanta on May 26-27. CLIAC makes recommendations to the Secretary of Health and Human Services (HHS), through the Centers for Disease Control and Prevention (CDC), concerning changes to the CLIA '88 regulations.

CLIAC recommendations are **not** binding upon CDC, but so far most of the Committee's decisions have been accepted. Even if adopted by CDC, CLIAC recommendations must still be approved by the Secretary of HHS before final publication in the Federal Register and subsequent implementation.

There are 20 positions on CLIAC, of which a majority (11) are physicians, four are Ph.D.s, three are MT(ASCP)s and one is a public member. A twentieth position on the committee has apparently been assigned to an "industry liaison", a representative from manufacturers and suppliers.

Following is a summary of the CLIAC recommendations adopted at the May 26-27 meeting:

Testing Personnel (High Complexity Testing)

* The equivalent of an associate degree is defined as 60 semester hours of college credit, including either 24 hours of medical technology or 16 hours of chemistry and 8 hours of biology , requiring either one year of clinical laboratory training including each of the laboratory specialties or three months of training in each specialty in which the individual performs high complexity testing. (It is not clear what constitutes acceptable training. Work experience may count, but a formal, written training program is advisable.)

* Until September 1, 1994, individuals who have completed accredited laboratory training programs, including one-year of military training, will qualify.

* Individuals with a high school diploma and appropriate laboratory training who are performing high complexity testing on the date that revised regulations are published may continue to perform high complexity testing indefinitely, provided the results of such testing are reviewed by a supervisor (general or technical) within 24 hours of performance.

* After the date revised regulations are published, laboratories may **not** continue to hire high school graduates to perform high complexity testing.

General Supervisor (High Complexity Testing)

* After a specified date (which was not specified by CLIAC), a bachelor's degree is required and clinical laboratory training/experience of not less than one year which could be either a 12-month clinical rotation in the specialties of chemistry, hematology, immunology, immunohematology, and microbiology or three months training in each specialty supervised with additional training/experience equal to at least one year.

* Also qualifying are individuals who on or before the date of publication of revised regulations were serving as general supervisor and meet one of the following requirements:

- Have earned an associate degree in laboratory science or medical technology, or equivalent, and have two years of laboratory training or experience in high complexity testing.

- Have graduated from an accredited laboratory training program,including military training, and have two years experience as a general supervisor of high complexity testing.

- A high school graduate, or equivalent, with laboratory training as described in section 493.1489(b) (4) (ii) of the CLIA regulations and a total of ten years experience in high complexity testing with at least 6 years experience supervising high complexity testing.

Note that associate-degreed individuals with 2 years of experience in high complexity testing qualify only if they are serving as a general supervisor on or before the date of the revised regulations. Therefore, be sure your associate-degreed technologists are given experience as supervisors, and document that experience, before these regulations are finalized.

* Reproduced with permission from the AAB UPDATE, Vol. 8, No. 9, May 28, 1993, published by the American Association of Bioanalysts, Suite 918, 818 Olive Street, St. Louis, Missouri 63101, (314) 241-1445

Earning the Associates Degree to meet CLIA Requirements.

Currently, CLIA '88 mandates that as of September 1, 1997, all laboratory personnel performing high complexity testing possess a minimum of an associate degree. This requirement is mandated unless laboratory personnel previously qualified, or could have qualified, as a technologist under previous federal regulations*. The associate degree must be from an accredited institution in either a laboratory science or medical laboratory science. (ref. Federal Register, Vol. 57. No. 40, February 28, 1992. p. 7183)

A National directory listing accredited colleges and universities offering an associate degree in medical laboratory technology (MLT) may be obtained for $35.00 by contacting: The National Accrediting Agency for Clinical Laboratory Science (NAACLS), 8410 West Bryn Mawr, Suite 670, Chicago, Illinois 60631. Telephone: (312) 714-8880. The National directory lists the names of all accredited institutions, addresses, program directors, and telephone numbers.

Alternately, information on colleges and universities in the United States offering an associate degree in the laboratory sciences may be obtained for $36.00 by contacting: The American Medical Association, Order Department OP417592, PO Box 109050, Chicago, Illinois 60610-9050.

Further information regarding laboratory personnel requirements may be obtained by contacting the Massachusetts Division of Health Care Quality: Telephone: (617) 726-5860.

* The two non-degree paths to qualify as a technologist under previous federal regulations include:

(1) passing the federally sponsored HEW/HHS examination for technologists; or,

(4) earning 90 semester hours (s.h.) of college credits with 16 s.h. of chemistry, 16 s.h. of biology, 3 s.h. of mathematics and a minimum of one year of clinical laboratory experience.

HIV Seroprevalence Studies in Newborns

There are several public health implications of seroprevalence studies and research on the early diagnosis of human immunodeficiency virus (HIV) in newborns. At least one of every 3000 Massachusetts births is an HIV-infected infant, an incidence comparable to congenital hypothyroidism (1/4000) or sickle cell anemia (1/3000). Unfortunately, HIV lacks definitive treatment (as in congenital hypothyroidism), and thus is a major source of morbidity and mortality in infants.

Studies of HIV and newborns present another dimension that distinguishes this disease from congenital hypothyroidism or sickle cell anemia. In the latter conditions the parents are usually unaffected. By contrast, all of the mothers of HIV-infected newborns are themselves infected. Furthermore, there are many infected mothers who do not pass an infectious dose of virus to their newborns but who themselves become sick during the early years of their children's lives. Because anti-HIV antibody of any infected mother passes to the newborn, it is detectable in screening studies. Therefore, batches of newborn sera tested anonymously are used to estimate the prevalence of HIV infection in women who give birth in Massachusetts. This study plan has been adopted by other countries and by most states under federal public health sponsorship.

The seroprevalence studies in newborns, as noted above, have provided a background for a merged interest in direct estimation of HIV-infection among HIV antibody-positive dried blood spots available as a byproduct of routine newborn screening for other conditions. Since April of 1992, all anonymous newborn specimens with positive HIV antibody results have been tested for the presence of HIV detectable by the polymerase chain reaction (PCR). Of the 211 specimens tested, 14 were PCR positive. The 14 PCR positives are believed to be only about half of the actual infections because our earlier studies showed that infected newborns test positive only about half as often as infected adults studied by PCR. Therefore, twice the observed rate of 14/211, i. e. 28/211 (13%), should be the corrected estimate, which provides an indication of the minimum transmission rate from infected mothers to their newborns during the study period.

Support for the studies from the National Institutes of Health will continue through October, 1993. The data generated during the past five years formed a major part of the basis for national deliberations on anonymous versus linked HIV screening of newborns. Recent thoughts on the topic were outlined in the Institute of Medicine's report, HIV Screening of Pregnant Women and Newborns, Chapter 4: "Reevaluating Newborn HIV Screening Policy".

Hemoglobinopathy Laboratory

On April 1, 1990, the New England Regional Newborn Screening Program implemented a program to test all newborns born in Massachusetts for sickle cell trait, sickle cell anemia and other hemoglobin conditions. The primary purpose of this program is to identify infants with sickle cell disease in order to provide them with penicillin prophylaxis and to ensure a comprehensive method of follow-up. Penicillin is provided free of charge for the first three years of life through the Massachusetts Department of Public Health and is available to those infants born in Massachusetts. According to a study published in 1986 in the New England Journal of Medicine (1), penicillin taken twice daily significantly reduces the number of serious life threatening bacterial infections associated with sickle cell disease.

The second purpose of the Program is to identify those infants with various traits (i.e., sickle cell trait) in order to offer genetic counseling, carrier testing and related health education. After the newborn's primary care physician has been notified of the infant's trait or disease status, the parents are sent a series of letters offering follow-up services from the Program. The Program attempts to contact parents over a three month period. If there is no response, or interest in receiving counseling, testing, or educational services, the infant's primary care physician is notified of all efforts made. At that point, test results and educational information are forwarded to the parents. These services are provided by trained hemoglobin trait counselors of the Program in cooperation with various satellite clinics.

In summary, for the three year period from April 1, 1990, through March 31, 1993, over 270,000 newborn specimens were tested for hemoglobin disorders. The laboratory has identified 3,722 clinically significant traits. More importantly, 149 hemoglobinopathies have been identified of which, 58 were sickle cell disease that were followed-up with preventive measures.

(1) New England Journal of Medicine, Vol. 314, No. 25, June 19, 1986: 1593-99.

STD Update

The trend in reported STDs has continued the decline that began two years ago. When comparing Week 23 of 1993 to its counterpart from 1992, there has been a 27% decline in infectious syphilis, a 23% decline in gonorrhea, and a 21% decline in chlamydia. A more complete display of reported STD morbidity is shown below.

DISEASE	WEEK 23 1993	WEEK 23 1992	% CHANGE
Inf Syphilis	249	342	-27
Gonorrhea	1266	1639	-23
PPNG	153	68	+125
Chancroid	1	6	-84
Chlamydia	3758	4780	-21
PID	74	59	+25

The great discrepancy in the trend is with penicillinase producing Neisseria gonorrhoeae (PPNG). There is an outbreak of PPNG in Massachusetts at this time. It appears to be localized in the Boston area, but we are tracking it carefully and compiling interview data as part of the investigation. It would be of immense help to us in our efforts to understand and then control this outbreak if all laboratories were sure to send ALL gonorrhea isolates to the State Laboratory for confirmation and typing. We will keep you posted of developments in this investigation.

NCCLS Updates Guideline on Blood Gas Analysis

NCCLS document C27-A, Blood Gas Pre-analytical Considerations: Specimen Collection, Calibration and Controls, addresses the major pre-analytical, operator-dependent, and instrument-dependent variables that must be examined within the field of blood gas and pH analysis. The document is intended primarily for clinical laboratory directors, medical technologists, cardiopulmonary technologists, respiratory therapists, physicians, nurses, and others involved in collecting and analyzing arterial blood for pH and blood gases.

C27-A addresses areas that must be considered when collecting the specimen, including the condition of the patient; collection variables and equipment; types of specimens; transportation requirements; and the handling of specimens in the laboratory. Calibration of the blood gas analyzer is addressed, including kinds of calibrants, methods of calibration, and potential sources of calibration error. Principles of an effective quality control program are outlined and recommendations are given. Sources of error in blood gas analyzers and requirements for commercial blood gas controls are also discussed.

NCCLS standards and guidelines can be obtained by contacting: NCCLS, 771 E. Lancaster Ave., Villanova, PA 19085 (212) 525-2435 FAX (215) 527-8399.

Salmonella enteritidis Update

Salmonella enteritidis has continued to be the organism responsible for a majority of foodborne cases of Salmonella in Massachusetts. To date it is the organism implicated in at least six alleged outbreaks. Salmonella enteritidis is responsible for approximately 30% of all Salmonella isolates submitted to the State Laboratory Institute for serotyping.

SLI Notes...

New QA/QC & Safety Officer

The State Laboratory Institute welcomes Peggy DiNatale, M.S., MT(ASCP), as the QC/QA Coordinator and Safety Officer. Ms. Dinatale, whose previous work includes bench and supervisory level positions in several clinical laboratories, is working to develop, implement and coordinate a comprehensive QA/QC program. The program has been well received by all laboratory staff.

New State Training Coordinator

The State Laboratory Institute and the National Laboratory Training Network (NLTN), welcome Garry R. Greer, as the new State Training Coordinator. Mr. Greer, has been a Public Health microbiologist for 15 years, and has served as General Laboratory Supervisor at a private clinical laboratory. In addition to internal training programs, Mr. Greer will work collaboratively with the NLTN to bring laboratory training programs, seminars, workshops and conferences to Massachusetts.

New Human Resource Generalist

The State Laboratory Institute welcomes Joanne Horgan, M.S., Human Resource Counseling, as a new addition to Personnel. Ms. Horgan comes to us from Massachusetts General Hospital Office of Employee Relations. She will be assisting Julie Schmitt with project coordination and implementation of staff development.

National Laboratory Training Network: New England ALTA News

Good Laboratory Practices to Assist Laboratories in Meeting CLIA Regulations-A Guide for Laboratories Performing Moderate Complexity Tests: This course, developed with input by a network of expert representatives from New England public health laboratories, physician office laboratories, HCFA, state survey agencies, ASTPHLD and CDC, has been conducted in Vermont, Maine, Connecticut, Massachusetts, and is scheduled to be conducted in New Hampshire. Participants' response to the course has been overwhelmingly positive. When asked if they will make changes in their procedures as a result of attending the course, over 90% indicated that they would do so. The course is especially useful to persons working in physician office laboratories, health clinics, and other non-hospital laboratories.

New England ALTA calendar

Good Laboratory Practices (see above)

Module 1 - 1/2-day workshop: Procedure Manuals, Preventive Maintenance, Quality Control

August 15	Lancaster NH	August 30	Rockville, CT
August 29	Danbury, CT	September 5	New Haven, CT

Module 2 - 1/2-day workshop: Personnel & Facility Standards, Patient Test Management, QA, Safety

August 22	Lancaster NH	September 14	Rockville, CT
September 13	Danbury, CT	September 19	New Haven, CT

Module 3 - 1/2-day workshop: Laboratory Methods & Techniques, Proficiency Testing, Inspections

August 29	Concord, NH	September 28	Rockville, CT
September 27	Danbury CT	November 2	New Haven, CT

New and Rapid Methods in Mycobacteriology
1 day workshop, June 18, State Laboratory Institute, Jamaica Plain, MA

Fluorescent Microscopy for MTB
1/2-day wet workshop, June 29, Burlington, VT

Flow Cytometry Immunophenotyping Quality Assurance/Quality Control
3-day wet workshop, June 28-July 1, University of Massachusetts, N. Dartmouth, MA

Parasitology
2-day wet workshop, August 16-17 Stonehill College, North Easton, MA

Cost Effective Community Hospital Microbiology
1 day seminar, October 8, VA Medical Center, White River Junction, VT

Upcoming Courses
Lead Methodology and Instrumentation

For more Information: Please call the New England Area Resource Office (617) 522-3700 ext. 211, for information on these and other training programs offered in the region, and for a flier about the National Laboratory Training Network.

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